I hereby certify that this correspondence for U.S. Patent Application No. 10/759,740, filed January 16, 2004 in re Yinghe Hu, *et al.* is being facsimile transmitted to the United States Patent and Trademark Office at facsimile number 571-273-8300 on July 13, 2006

By: Jill R. Clarke
Jill Clarke

PATENT
Attorney Docket No.: P1125US00



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re application of: | Examiner: KETTER, James S. |
| Yinghe Hu, *et al.* | Art Unit: 1636 |
| Application No.: 10/759,740 | Confirmation No.: 6897 |
| Filed: January 16, 2004 | |
| For: Universal G-Protein Coupled Receptor Reporter Constructs | **Response to Office Action** |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sirs:

This is responsive to the non-final office action mailed April 13, 2006 in the above-captioned patent application. The only issue raised in the office action in the above-captioned patent application is a claim rejection under 35 USC 112 alleging that the subject application failed to comply with the written description requirement.

Applicants note that an identical rejection was previously raised in the office action mailed June 29, 2005. Upon Applicants' submission of a response on September 29, 2005, the rejection was withdrawn by the Examiner as indicated in the office action mailed December 23, 2005. Applicant further note that, compared to the previously withdrawn rejection, the instant office action does not provide any new ground or reasoning in rendering the same rejection. Rather, precisely the same alleged deficiency in written description of the subject patent application was set forth in the instant office action. As such, Applicants reiterate herein the arguments submitted in the previously filed response, and respectfully request withdrawal of the instant rejection.

In rejecting the pending claims as lacking written description support, the office actions asserted that the multiple response element (MRE), cAMP-response element (CRE) and the serum response element (SRE) recited in the claims are undefined in the specification or the claims. It was also asserted in the office actions that these terms "would embrace any sequence that is labeled an MRE, CRE and SRE," and that "the specification does not disclose any teachings as to the structures of these sequences and how the structures of these sequences relate to their function." It was further alleged in the office actions that "the specification neither described the complete structure of a representative number of species" nor "a representative number of species in terms of partial structure and relevant identifying characteristics." As detailed below, Applicants respectfully disagree with each of these assertions.

First, the MRE, CRE and SRE response elements recited in the claims are NOT "any sequences merely labeled "MRE/CRE/SRE" as asserted in the office actions. To the contrary, they are technical terms that are all well known and recognized in the relevant art. Each of these response elements has well defined function and structure characteristics. For example, SRE was reviewed as a well recognized technical term in the scientific literature as early as 1992. See, e.g., Trends, *The serum response element*, Biochem Sci. 17:423-6, 1992. In addition, the well defined function of this response element is also reflected in its definitions present in several dictionaries (see the attached printout sheets of On-line Medical Dictionary and Dictionary of Cell and Molecular Biology). For example, it is defined in the Dictionary of Cell and Molecular Biology (Online) as "DNA motif found (for example) in the c-fos promoter, which is bound by the serum response factor."

Likewise, MRE and CRE are also scientific terms well recognized by the skilled artisans in the filed of molecular biology. For example, there have been a number of scientific articles devoted to reviewing the structure and function of cAMP response elements since 1994. See, e.g., Vallejo, *Transcriptional control of gene expression by cAMP-response element binding proteins*, J Neuroendocrinol. 6:587-96, 1994; and Habener et al., *cAMP-dependent regulation of gene transcription by cAMP response element-binding protein and cAMP response element modulator*, Vitam Horm. 51:1-57, 1995. CREs from different transcription regulatory systems have since been reported, all with identical function and consensus sequences. Similarly, the structure and function of MRE was reported in the literature as early as 1989. See, e.g., Ray et al., *A multiple cytokine- and second messenger-responsive element in the enhancer of the human interleukin-6 gene: similarities with c-fos*

*gene regulation*, Mol Cell Biol. 9:5537-47, 1989. MREs from different cells that have been reported in the literature all share common structure feature (i.e., sequences) and identical function in regulating transcription. Thus, rather than embracing any sequence merely labeled MRE/CRE/SRE, each of the three response elements recited in the claims only encompass a limited number of art recognized DNA motifs. In addition to performing the same or similar function in regulating transcription, members in each of the three classes of response elements all share common structure features (more details below).

Applicants further note that, contrary to the statement made in the office actions, the subject specification has provided ample teachings and description of these response elements. The description of these transcription control elements in the specification is consistent with their well defined functions and structures. Specific structures of representative members of these response elements were also set forth in the specification. For example, it was taught in the specification (e.g., at page 8, line 26 to page 9, line 5) that "serum response elements are promoter elements required for the regulation of many cellular immediate-early genes by growth." The specification also noted that "SREs from various genes (e.g., c-fos gene) have been described in the art, e.g., in Treisman, R., *The serum response element*, TIBS, 17:423-426, 1992." The specification further provided the specific nucleotide sequences of a few SREs, e.g., SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 5.

For MREs, the specification (e.g., at page 9, lines 6-17) disclosed that they "are enhancer elements that confer responsiveness to multiple cytokines and second messengers." Two specific examples of MREs and their sequences were also provided in the specification via incorporation of references cited therein. The specification (e.g., at page 9, lines 18-26) also taught CREs are transcription regulatory sequences that interact with transcription factors which mediate signal transduction involving cAMP. It was further disclosed in the specification several exemplary CRE sequences, e.g., TGACGTCA, TTACGTCA, TGACGTCT, TGACGTAG, and CTGCGTCA.

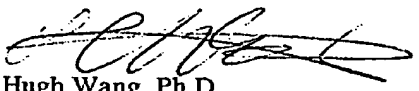
Applicants also urge the Examiner to note that the currently rejected claims are not directed to the SRE, MRE and CRE transcription control elements per se. Rather, the claims are directed to polynucleotide constructs that comprise these response elements and methods of using such constructs. Patentability of the claimed invention does not preside on the exact sequences of the response elements employed in the polynucleotide constructs. Instead, patentability is predicated on the novel concept of employing all three kinds of response elements in a single construct for detecting activities of different types of GPCRs in

a single functional assay. Thus, so long as each employed response element performs its well defined function, the exact nature of the response elements (e.g., their sequences) used in the construct is not essential or critical to the claimed invention. It is readily apparent that any of the art recognized MRE, CRE and SRE elements can be employed to produce the claimed polynucleotide constructs and methods, with the same or similar effect.

In view of the foregoing, it is readily apparent that the subject specification has provided sufficient description of the presently claimed invention. As such, Applicants request that the instant rejection be withdrawn and a formal Notice of Allowance be issued.

If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-812-1539.

Respectfully submitted,



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